



STATE MEDICAID DUR BOARD MEETING
THURSDAY, November 10, 2005
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125



MINUTES

Board Members Present:

Charles M. Arena, M.D.
Lowry Bushnell, M.D.
Derek G. Christensen, R.Ph.
Dominic DeRose, R.Ph.
Karen Gunning, Pharm D.

Bradford D. Hare, M.D.

Jeff Jones, R.Ph.

Wilhlem T. Lehmann, M.D.

Joseph K. Miner, M.D.

Colin B. VanOrman, M.D.

Board Members Excused:

Bradley Pace, PA-C

Dept. of Health/Div. of Health Care Financing Staff Present:

Rae Dell Ashley, R.Ph.

Tim Morley, R.Ph.

Richard Sorenson, R.N.

Suzanne Allgaier, R.N.

Nanette Waters

Other Individuals Present:

Craig Boody, Lilly

Tim Smith, Pfizer

Pierre Thoumsin, Amgen

Jeff Buel, J&J

Bridget Olson, Lilly

Alan Bailey, Pfizer

Nash Halem, Takeda

Mack Gift, MHAU

Tim Clark, Amgen

Todd Christensen, Takeda

Stephanie Kendall, Janssen

Dana Garet, Lilly

Matt Johnson, Takeda

Oscar Fuller, CMS

Owen Boyer, Pfizer

Alan Sloan, Purdue

Kevin Galbraith, Pfizer

Cap Ferry, LES

Kristin Hindert, MD

Lissa Martin, MHAU

Meeting conducted by: Lowry Bushnell

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1. Minutes for October 13, 2005 were reviewed, corrected and approved.
 2. Housekeeping- Reminder: Information in packets will not be duplicated to save on paper. Please bring mailed information with you to the Board meetings.

The December meeting will be 12/8 with the barbecue dinner served from 5:00pm until 6:30pm. The Dur Board meeting will begin at 6:30pm. It will be held at Joe Morley's Barbecue 100 West 7720 South in Midvale.

3. Business Carried Forward:

Gabapentin off-label use; Lyrica and Cymbalta- year to date usage data was presented to the Board along with trend data; the problem was restated by Tim: gabapentin has much off-label use and is less expensive than Cymbalta and Lyrica. Do we control the use of Cymbalta and Lyrica and thereby all their other indications in order to limit the off-label use to a lesser expensive gabapentin; do we restrict the usage of all of them to control off-label use as group; or do we impose no restrictions because of non- neuropathic indications? RaeDell noted that regulations require that Medicaid provide coverage according to approved FDA indications. Overriding that requirement may be done on a case by case basis when substantiated, but that is to be the exception not the rule. The Board may be able to approve overriding all use for a specific indication, but cannot apply that action across the board as the rule. Brad noted that neuropathic pain is neuropathic pain regardless of its source and they all behave and are treated about the same. He stated that to try and distinguish between the differing types is silly and that he feels that neuropathic pain as a general category is a responsible consideration. He notes that the differing drugs have differing mechanisms of action as well and that to try and limit the treatment to one is a simplified approach to a complicated situation, i.e. if one doesn't work you switch to another, or you add one to another using different sequences and combinations. Brad maintained that due to dosing needs for gabapentin that Lyrica may be a lesser expensive alternative. Lowry requested Journal articles supporting uses in neuropathic pain from anyone who knows of them. Dr. Sharon Weinstein from the U of U mentioned recent articles, one from the American Academy of Neurology- a practice parameter on the treatment of neuropathic pain which includes as first line treatment options gabapentin, pregabalin, opioids, and topical lidocaine patches. She emphasized the opioid sparing effects of these agents. Karen suggested obtaining information regarding maximum and appropriate dosing guidelines, and combined uses of Cymbalta and Lyrica. Brad noted that there are good studies supporting improved efficacy with the combined use of gabapentin and desipramine and suggested that similar extrapolations could be made for Cymbalta-desipramine combination. Dr. Weinstein said there are very few studies looking at combined therapy with anti-convulsants and anti-depressants in general, but that most treatment regimens include one drug from each of those categories for the treatment of neuropathic pain. Karen confirmed that there is no rationale for using Lyrica with Neurontin. Dosing differences between gabapentin and Lyrica were discussed and how it impacts pricing. Karen recommended that a comprehensive recommendation be provided as a provider educational material after the college of Pharmacy finishes its criteria review of this category. Lowry reminded us that Cymbalta use as an anti-depressant is still a separate issue. Tim noted that the use of Cymbalta continues upward and that its use as an antidepressant vs a neuropathic pain treatment cannot be easily separated. Karen suggested that quantity limits are an easier tool to employ in the absence of other actions for restrictions. Discussion of appropriate quantities for Cymbalta use were discussed; the inappropriate use of Cymbalta with other SSRI's or Effexor were discussed.

4. **Sedative/Hypnotics- Limit review-** Tim requested Board review for this category for appropriate use where Medicaid currently covers 30 units in 30 days. None of the medications in this category have indicated uses beyond acute conditions. Other states limit the number of doses below what Utah does and the number of refills. Because of the high

number of tablets Utah allows, there has not been much strain on the part of providers and patients in terms of access. Lowry noted that the reality of clinical practice is that there are people that benefit greatly from continuous uses over years. Karen stated that acute safety issues have been addressed by looking at inappropriate very high doses and further restrictions would create a lot of pushback from the provider and patient communities. Lowry suggested that doing so would result in more people being on atypicals for sleep. RaeDell asked if the Board wants to handle the many requests that come to us for higher doses. Both Lowry and Karen say that they prefer being hard-nosed about limits currently in place. The case of Ambien CR was raised and the consensus was that it is an inappropriate dosing form that eliminates the whole basis of its initial introduction in the first place. Nash Halem, the Takeda rep addressed the Board regarding Rozerem long term use approval. No action was moved for this item.

5. **Step-Therapy: Anti-psychotics-** The reason for this item was an article appearing in the New England Journal of Medicine which showed that the older anti-psychotics prove to be just as effective as the new atypicals. Should there be therefore some type of step therapy for the anti-psychotic classes for anti-psychotic naive patients?

The new atypicals still consume one-fourth of the Medicaid budget. Lowry appreciated the attention drawn to the older drugs because he feels there still is a place for the older drugs and this study underscores that, however he doesn't feel the study is strong enough to initiate a policy action. Karen added that side effects still will have an impact on the use of these drugs. When weight gain is compared against EPS as potential side effects, an easy observation results. Lowry observed that practice would benefit from what occurred with risperidone where recommended doses were lowered and side effects diminished yet efficacy remained. Karen noted that a bigger issue is the combined use of Atypicals, and suggested that would be a better arena for action. Dr. Michael Stevens addressed the Board. He presented an opinion on the CATIE study from the New England Journal article. He had some misgivings about the study and study design. Dr. Kristina Hindert, Medical Director of the Childrens Center, and consultant to the Developmental center, the State Hospital and to the Division of Mental Health addressed the board regarding Comprehensive NeuroScience project and requested the board wait upon results from that project before making any decisions. She notes that for children the only area with evidenced based data involves atypicals and removal as first line agents for that patient group takes away the whole research base for prescribing decisions for children even though they are not included in FDA labeling. Lowry asked if there were anyone present that wanted to advocate a rash motion. No motions were forwarded. Lowry also pointed out that the logic of not mixing the first generation anti-psychotics in combination therapy cannot be extended to the mixing of atypicals which may have a greater basis in clinical logic.

6. **Juvenile Rheumatoid Arthritis criteria- biological meds-** the criteria for JRA needs some work. As currently composed it doesn't work well for this component of RA vs all the other forms of RA, plaque psoriasis and psoriatic arthritis. RaeDell shared the viewpoints of Dr. Bohnsack, a juvenile arthritis specialists at the U of U, who has pointed out the inadequacies of the current criteria. It is proposed that we create a separate PA category for these drugs for JRA: children 4 to 17 years of age after being seen by a specialist and failure on MTX or one other DMARD. This criteria would be set apart from the other criteria for these drugs. Motion was made and passed to approve the proposal.

As a footnote, Brad made mention of the past issue surrounding the generic mandate law, as it concerns situations where the brand name drug may cost less than the generic. His question devolves

upon the fact that a change is needed in the law and who would be the contact to effect a change. Karen suggested that Roz McGee would be the best contact. A single line change is all that is required.

Motion made and passed to adjourn.

Next meeting set for December 8, 2005 at 6:30pm to be held at Joe Morley's Barbecue (no relation-really), 100 West 7720 South Midvale, Utah.

Meeting adjourned.

